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## Press Releases

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### **INSOUND MEDICAL RECEIVES FDA CLEARANCE TO MARKET THE WORLD'S FIRST EXTENDED-WEAR HEARING DEVICE**

#### **Totally Invisible Device Can Be Worn Continuously and Comfortably For Up to Four Months**

Newark, CA – December 2, 2002 -- InSound Medical, Inc. today announced that the InSound XT Series Hearing Device, the first extended-wear hearing device, has received clearance from the U.S. Food and Drug Administration (FDA) as a treatment for the estimated 28 million Americans with hearing impairment. Designed for all hearing impaired patients, except those with a profound loss, the InSound XT is worn invisibly and continuously, without removal, deep inside the ear canal for up to four months.

According to a recent study by the National Council on Aging, the hearing impaired who do not seek treatment tend to lead less satisfactory lives. Hearing impaired persons ages 50 and over who did not use hearing aids reported significantly higher rates of depression, anxiety, paranoia, reduced social activity and emotional insecurity than those that wore hearing aids.

"By removing the social stigma associated with a visible hearing aid, we expect the InSound XT to provide the hearing impaired with a richer and fuller life," said Adnan Shennib, InSound Medical President and Chief Executive Officer. "The device is so unobtrusive and hassle free that a user can shower, sleep and swim with the device in the ear".

Historically, hearing aid users have been dissatisfied with their hearing aids due to discomfort, sound quality, battery life and conspicuous designs that made it difficult to hide their impairment from others. In fact, approximately 80 percent of the 28 million hearing impaired individuals in the U.S. have refused to purchase a hearing device of any kind.

"The InSound XT has the potential to overcome many of the problems that currently prevent the hearing-impaired from obtaining hearing devices. It is invisible, comfortable, overcomes the 'hollow sound' associated with previous devices and does away with daily cleaning and frequent battery changes," stated Robert W. Sweetow, Ph.D., Director of Audiology and Professor of Otolaryngology at the University of California, San Francisco Medical Center.

In one visit, the InSound XT is custom-fitted to each patient and then inserted deep in the canal by an otolaryngologist, in collaboration with an audiologist, in a three-minute, non-surgical procedure requiring no anesthesia. The device is placed very close to the eardrum, improving upon the current standard of sound quality by increasing high frequency amplification and minimizing feedback. Upon battery depletion, a new device is re-inserted and the old device is discarded.

"I believe that ENTs, audiologists and, most importantly, patients will herald the arrival of the InSound XT," stated Robert Schindler, MD, Professor and Emeritus Chairman of the Department of Otolaryngology, UCSF. "It is a groundbreaking development for the hearing impaired."

The InSound XT solves the extended-wear challenge through micro-miniaturization and an ultra-low power chip, which requires less than 10 percent of the energy of conventional hearing aids, extending the lifespan of the battery to up to four months from the typical several days. Clinical studies are ongoing at the University of California, San Francisco and at InSound Medical. The San Francisco Bay area will be the first test market for the InSound XT in 2003.

#### **About InSound Medical**

InSound Medical, Inc. is the developer of extended-wear hearing products, which are designed to operate continuously for several months inside the ear canal. The company's advanced hearing devices will be fit by ear, nose and throat (ENT) doctors, in collaboration with affiliated audiologists. The company's proprietary products and distribution channels are designed to provide alternatives for the growing hearing-impaired population, estimated at 28 million in the U.S., the vast majority of whom are generally dissatisfied with or unable to utilize conventional hearing aid products, according to industry reports.

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### **InSound® Medical to Present at the MedTech Insight**

#### **Conference on Medical Technology "Investment in Innovation"**

- **InSound to Preview the World's Smallest and Most Inconspicuous Hearing Devices**
- **New Extended-Wear Hearing Technology Worn Continuously, Even During Shower and Sleep**

Newark, CA, February 20, 2002, InSound Medical, Inc., the inventor of the InSound® Extended-Wear hearing products, today announced that it will present at the MedTech Insight Conference on Medical Technology to be held in Irvine, California February 20-22. Adnan Shennib, President & CEO will preview the company's plans to launch the world's first extended-wear hearing devices later this year.

#### **Revolutionary Core Technology**

At the heart of the InSound hearing device is a custom integrated circuit (IC) which operates at miniscule energy requirements estimated at less than 10% of that consumed by conventional hearing aids. The device also incorporates a proprietary long-life battery, which extends the operation from the usual 4 - 10 days to 4 - 6 months. The unprecedented level of miniaturization and integration has resulted in the world's smallest hearing device weighing less than 1 gram, including the battery. The unique ultra low power IC and long-life battery, in conjunction with the exceptional proximity of the miniature device to the eardrum, allows the InSound hearing device to operate inside the ear canal continuously for 4 to 6 months.

Today, most person's with hearing impairment refrain from using hearing aids due to limited performance, discomfort of wear, high costs and stigma. "InSound Medical has addressed each of these issues as well as the hassles associated with wearing a hearing device", stated Adnan Shennib. The "hassles" of ownership include daily insertion and removal, frequent repairs, and replacement of very small batteries. In contrast, the InSound device is worn invisibly and continuously in the ear canal, even during showering, swimming, and sleep. The device is disposable after 4 to 6 months of continuous wear thus never requiring repairs or battery changes.

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### **InSonus Medical, Inc. Completes Name Change to InSound® Medical, Inc.**

January 17, 2002 – Newark, CA – InSonus Medical announced today that the Company has completed its name change to InSound Medical. "The name change reflects our desire to build a distinctive brand for our company and its products as we prepare to launch the world's first extended-wear hearing products," stated Adnan Shennib, president and chief executive officer.

#### **About InSound Medical**

InSound Medical, Inc. is a start-up company developing innovative hearing devices by combining electronic implant technologies with high fidelity audio to produce the world's smallest hearing devices that operate continuously for up to six months inside the ear canal. The company's advanced hearing devices will be fitted by Ear, Nose, and Throat (ENT) doctors, in collaboration with affiliated Audiologists. The company's proprietary products and distribution channels are designed to provide alternatives for the growing hearing-impaired population, estimated at 28 million in the U.S., the vast majority of whom are generally dissatisfied with or unable to utilize conventional hearing aid products, according to industry reports.

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### **InSonus Medical, Inc. Appoints Susan Whichard Vice President of Marketing and Sales**

October 10, 2001 – Newark, CA -- Susan Whichard has been appointed Vice President of Sales and Marketing for InSonus Medical announced Adnan Shennib, president and chief executive officer. Prior to joining InSonus Medical, Ms. Whichard has worked with Sound ID and GN ReSound as Vice President of Marketing. While at ReSound from 1994 to 1999, sales of the company's advanced products reached \$150M. Becoming one of the largest hearing instrument players in the United States, ReSound was acquired by Great Nordic (GN) in 1999. Prior to joining ReSound, Ms. Whichard was the founder and director of the Lewis-Gale Audiology Clinic, a division of the largest multi-specialty clinic in Virginia, providing audiological and hearing instrument services directly to the public and via a network of affiliated ENT (Ear-Nose-Throat) physicians.

"We are very pleased to have Susan join our executive team to lead our sales and marketing efforts. Her depth of knowledge and experience is well recognized in the hearing healthcare field," stated Adnan Shennib.

"I am pleased to be part of the InSonus team that is developing innovative products for persons with hearing loss. InSonus will bring to market the world's smallest and most inconspicuous hearing devices," stated Susan Whichard. "Unlike conventional hearing

aids, the InSonus hearing device is worn by the user continuously even during sleep, shower and swimming. This will be the first truly "hassle free" solution for millions of persons with hearing impairment who are today going untreated".

Ms. Whichard is a member of the American Academy of Audiology and is a past President of the Academy of Dispensing Audiologists. She also resided on the editorial board of various health care journals including Audiology Today. Ms. Whichard is a recognizer speaker and lecturer on topics related to hearing healthcare. She holds an M. S. Degree in Audiology from Radford University and a B.S. in Speech & Hearing from East Tennessee State University.

### About InSonus Medical

InSonus Medical, Inc. is a start-up company developing innovative hearing devices by combining electronic implant technologies with high fidelity audio to produce the world's smallest hearing devices that operate continuously for up to six months inside the ear canal. The company's advanced hearing devices will be fitted by Ear, Nose, and Throat (ENT) doctors, in collaboration with affiliated Audiologists. The company's proprietary products and distribution channels are designed to provide alternatives for the growing hearing-impaired population, estimated at 28 million in the U.S., the vast majority of whom are generally dissatisfied with or unable to utilize conventional hearing aid products, according to industry reports.

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## INSONUS MEDICAL COMPLETES \$7 MILLION ROUND OF FINANCING, FUNDED BY ESSEX WOODLANDS HEALTH AND PIPER JAFFRAY VENTURES

MAY 31, 2001 – Newark, CA -- InSonus Medical, Inc. has completed a \$7 million round of private financing to complete the development of world's smallest and most inconspicuous *hearing devices* for the hearing impaired. The round was led by Essex Woodlands Health Ventures, which also participated in the previous round. "We are pleased with our initial investment in InSonus with progress made exceeding our expectations," stated Jim Currie, Managing Partner of Essex Woodlands Health Ventures, an investment firm focusing exclusively on the health care industry. "We expect InSonus to play a significant role in the hearing aid market."

The financing was joined by US Bancorp/Piper Jaffray Ventures, also a major health care investment firm. "We are very excited to join InSonus in their quest to revolutionize the hearing aid business. We believe that their talented team is on the cusp of introducing revolutionary products that will ultimately solve many of the consumer dissatisfaction issues that have plagued this industry," stated Ned Scheetz, Managing Director with Piper Jaffray Ventures. "We think InSonus has the best shot of growing market penetration well beyond today's 20% level. We have great confidence that the InSonus team will continue to exceed their milestones as they move forward with their ambitious goals."

"We are very pleased to have Essex Woodlands and Piper Jaffray participate in this round, particularly when considering their depth of knowledge and experience in the health care business," stated Adnan Shennib, President and Chief Executive Officer of

InSonus Medical.

### About InSonus Medical

InSonus Medical, Inc. is a start-up company developing innovative hearing devices by combining electronic implant technologies with high fidelity audio to produce the world's smallest hearing devices that operate continuously for up to six months inside the ear canal. The company's advanced hearing devices will be fitted by Ear, Nose, and Throat (ENT) doctors, in collaboration with affiliated Audiologists. The company's proprietary products and distribution channels are designed to provide alternatives for the growing hearing-impaired population, estimated at 28 million in the U.S., the vast majority of whom are generally dissatisfied with or unable to utilize conventional hearing aid products, according to industry reports.

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### **InSonus Medical Announces Plans to Develop the World's Smallest and Most Inconspicuous Hearing Devices**

- **Microsemi Corporation to Develop Ultra Low Power Sound Processing for InSonus Medical**
- **Extended Wear Hearing Technology Stays in the Ear Canal for Up to Six Months**

AUGUST 11, 2000 – Newark, CA -- InSonus Medical, Inc. has announced its collaborative program with Microsemi Corporation (Nasdaq: MSCC) to develop the world's smallest and most inconspicuous hearing devices. The InSonus products, currently under development, will represent the industry's first extended-wear hearing technology designed to operate continuously deep in the ear canal for up to six months. The advanced family of hearing devices will be fitted by Ear, Nose, and Throat (ENT) doctors in collaboration with affiliated Audiologists.

Microsemi Corporation will design and manufacture the ultra low power integrated circuit for the InSonus advanced hearing aid at its Micro Power Products Division in Carlsbad, CA. "We're particularly pleased to become part of the InSonus development team as they move their innovative concepts from the clinical research stage into the commercial marketplace," said Ron Courtois, Micro Power Products general manager. "We see InSonus as offering differentiated products for the rapidly growing market of hearing-impaired consumers."

InSonus Medical, Inc. is a venture backed start-up company developing innovative hearing devices by combining low power implant electronic technology with high fidelity audio to produce the world's most efficient and smallest hearing enhancement devices weighing less than 1 gram including the battery. These ultra-miniature devices will operate at far less battery power, estimated at only 10% of the rates consumed by conventional hearing aids. The unique ultra low power design allows the hearing device to operate inside the ear canal continuously for up to 6 months before battery replacement.

"We are very delighted to collaborate with Microsemi Micropower on the development of our proprietary hearing technology. The development team at Microsemi Micropower is exceptionally talented, which enabled us to rapidly move forward with our IC

development program. The Microsemi Micropower team certainly demonstrated depth of knowledge and experience in high fidelity audio and ultra-low power design," stated Adnan Shennib, Founder and President of InSonus Medical, Inc.

### About InSonus Medical

InSonus Medical, Inc. was founded in 1998 to develop and market minimally invasive hearing products for the rapidly growing hearing-impaired population estimated at 28 million in the U.S. alone. The company's proprietary products and distribution channels are designed to provide alternatives for the hearing impaired who are generally dissatisfied with or unable to utilize conventional hearing aid products, according to industry reports. The company is also developing a proprietary fitting system which allows medical doctors, in collaboration with audiologists, to dispense advanced hearing products in a single visit and under 1 hour. The company's "instant" fitting process is in stark contrast with conventional methods that require multiple visits spanning a period of 3-8 weeks. InSonus has filed key patents covering its novel designs and procedures.

### About Microsemi

Microsemi is a leading designer, manufacturer and marketer of analog, mixed-signal and discrete semiconductors. The company's semiconductors manage and regulate power, protect against transient voltage spikes and transmit, receive and amplify signals. Microsemi products include individual components as well as complete circuit solutions that enhance customer designs by providing battery optimization, reducing size or protecting circuits. Markets the company serves include medical, mobile connectivity, computer/peripherals, telecommunications, industrial/commercial, space/satellite and military. Microsemi Corporation, Santa Clara, CA- (714) 979-8220.  
[www.microsemi.com](http://www.microsemi.com)

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## INSONUS MEDICAL, INC. COMPLETES \$5 MILLION IN FINANCING TO DEVELOP INNOVATIVE EXTENDED WEAR HEARING TECHNOLOGY

DECEMBER 15, 1999 -- Hayward, CA -- InSonus Medical, Inc. has completed a \$5 million round of private financing to develop *extended wear hearing products* for the hearing impaired. The company's proprietary products, once fully developed, will be the smallest and most inconspicuous on the market and will be fitted by Ear, Nose, and Throat (ENT) specialists in collaboration with affiliated Audiologists. "Our minimally invasive hearing products will allow the hearing impaired person to continuously wear a totally invisible hearing device for up to 6 months, without the hassles of daily insertion and removal," stated Adnan Shennib, Founder and President of InSonus Medical. The investors in this round included venture capitalists, investment funds and ENT physicians.

"I am very excited about being involved with this revolutionary concept in hearing technology. It has the potential of helping millions of people who currently can't or won't wear an existing hearing aid," stated Robert Schindler, Professor and Chairman Emeritus of the Otolaryngology (ENT) Department at the University of California, San Francisco (UCSF) Medical Center. "The fitting process is also revolutionary, allowing a patient to be fitted with a superior hearing device in just one visit. The involvement of ENT

physicians in this process will help many hearing impaired individuals become hearing aid users, including many elderly individuals who don't have the manual dexterity to wear a conventional hearing aid," according to Dr. Schindler.

### About InSonus Medical

InSonus Medical, Inc. is a start-up company developing innovative hearing devices by combining electronic implant technologies with high fidelity audio to produce the world's smallest hearing devices that operate continuously for several months, and ultimately up to 1 year, before battery replacement. The company is also developing a proprietary fitting system which will allow the dispensing of its advanced hearing products in a single visit under 1 hour. The company's rapid fitting process is in stark contrast with conventional methods which require multiple visits spanning a period of 3-8 weeks. The Company's proprietary products and distribution channels are designed to provide alternatives for the growing hearing impaired population estimated at 28 millions in the U.S., the vast majority of the whom are generally dissatisfied with or unable to utilize conventional hearing aid products, according to industry reports.

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## Care for Your Hearing

FREE Hearing Test

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Care for Your Hearing Aid

Maintenance Tips ▶

Repairs & Troubleshooting

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☐ Request Info

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## Maintenance Tips

Just follow these simple guidelines to protect your Miracle-Ear hearing aid system from everyday wear and tear:

- Thoroughly clean your hearing aid daily with a dry cloth.
- Never immerse your hearing aid in water. Do not wear it while taking a bath or shower or while swimming. Do not expose it to excessive moisture of any kind.
- Never apply hair spray while wearing hearing aids.
- Do not expose your hearing aid to excessive heat, such as a stove or open fire.
- Unless you're wearing the hearing aid at the time, do not expose it to extreme cold (0 degrees or less F)
- Avoid dropping your hearing aid on hard surfaces.
- When not in use, remove the battery and store your hearing aid in the case provided by your Miracle-Ear representative.
- Put away hearing aids and batteries, out of reach of pets and children.

Schedule  
Consultation

Select a State

Enter Zip  
Code

Or call us  
877-26

## How to Clean Your Hearing Aid

- Wipe your hearing aid or earmold and tubing every day with a clean, soft cloth.
- Clean the receiver and vent openings with an appropriate wax removal tool, available at your local Miracle-Ear Hearing Aid Center. Make sure you received proper instruction from the Miracle-Ear representative to prevent damage to your receiver.
- We recommend you clean your hearing aid daily with a disinfectant wipe or tissue sprayed with disinfectant, which you can find at your local Miracle-Ear Hearing Aid Center.

## Battery Care

- When you remove your hearing aids, turn them off. If they don't have an on/off switch,



then turn them off by opening the battery door.

- Remove the battery at night, or whenever the hearing aid is not used for an extended period, and store the aid in a cool, dry place.
- Keep the battery compartment clean and dry.
- Always wipe the battery clean before inserting.
- Discard used batteries carefully in a place where they cannot come into contact with infants, small children, pets or others who might accidentally swallow them.\*

\* Hearing aid batteries are dangerous if swallowed. In the event that a hearing aid battery is ingested, see a doctor immediately, or call the National Button Battery Hotline at 202-625-3333.

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## Harvey, Dionne N.

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**From:** contact@america-hears.net  
**Sent:** Friday, December 19, 2003 4:22 PM  
**To:** Harvey, Dionne N.  
**Subject:** RE:

Wearing hearing aids for the first time takes some getting accustom to.  
But in the long run can be warn all day. Taking them out only to sleep.  
Carter  
America Hears  
800 492-4515

-----Original Message-----

**From:** Dionne.Harvey1@USPTO.GOV [mailto:Dionne.Harvey1@USPTO.GOV]  
**Sent:** Friday, December 19, 2003 3:53 PM  
**To:** contact@america-hears.net  
**Subject:**

how long can the hearing aid be worn without removal, before irritation  
to  
the ear?

Thanks, D. Harvey